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FILING DATE FIRST NAMED INVENTOR CONFIRMATION NO. APPLICATION NO. ATTORNEY DOCKET NO. 10/763,974 01/22/2004 Hassan Pajouhesh 381092001600 7894 **EXAMINER** 25225 7590 08/02/2006 MORRISON & FOERSTER LLP KOSACK, JOSEPH R 12531 HIGH BLUFF DRIVE ART UNIT PAPER NUMBER SUITE 100 SAN DIEGO, CA 92130-2040 1626

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)
Office Action Summary		10/763,974	PAJOUHESH ET AL.
		Examiner	Art Unit
		Joseph Kosack	1626
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).			
Status			
1)⊠	Responsive to communication(s) filed on 23 Ju	•	
, —	,	action is non-final.	
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is		
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.			
Disposition of Claims			
 4) Claim(s) 1-20 is/are pending in the application. 4a) Of the above claim(s) 18-20 is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 1-17 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. 			
Application Papers			
9) The specification is objected to by the Examiner. 10) The drawing(s) filed on <u>22 January 2004</u> is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).			
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.			
Priority under 35 U.S.C. § 119			
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 			
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3/17/04 & 8/15/05. 4) Interview Summary (PTO-413) Paper No(s)/Mail Date 5) Notice of Informal Patent Application (PTO-152) 6) Other:			

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DETAILED ACTION

Claims 1-20 are pending in the instant application.

Amendments

The amendment to the claims filed on June 23, 2006 has been acknowledged and has been entered into the record.

Election/Restrictions

Applicant's election with traverse of Group I (Claims 1-17 in part) along with an election of species of compound P2 in Figure 1 of the drawings in the reply filed on June 23, 2006 is acknowledged. Applicant's arguments have been considered, but were not found to be persuasive.

The requirement is still deemed proper and is therefore made FINAL.

Status of the Claims

Claims 1-20 are pending in the instant application. Claims 1-17 (in part), and Claims 18-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in the structure and element and would require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

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Pursuant to Applicant's election of a species, the scope of the invention will be limited to the following substitutions of the base structure

W is L^2 -A³;

- L¹ and L² are optionally substituted C₁-C₅ alkylene with no carbons
- A¹, A², and A³ are phenyl;

replaced by a heteroatom;

- X¹ is CR³;
- all other substituents are as defined.

As a result of the election and the corresponding scope of the invention defined supra, the remaining subject matter of Claims 1-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non-elected inventions. The withdrawn compounds contain varying functional groups such as pyrimidinyl, piperidinyl, imidazoyl, pyrrolidinyl, etc, which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classification of these functional groups in the U.S. classification system, i.e. class 544 subclass 244(+) (diazines), class 546 subclass 184(+) (piperidines), 546 subclass 249(+) (pyridines), etc. Therefore the subject matter which are withdrawn from consideration as being non-elected subject matter differ materially in structure and composition and have been restricted properly a reference which

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anticipated but the elected subject matter would not even render obvious the withdrawn subject matter and the fields of search are not co-extensive.

Information Disclosure Statement

The Information Disclosure Statements that were received on March 17, 2004 and August 15, 2005 have been considered fully by the Examiner.

Claim Objections

Claims 1-17 are objected to for containing elected and non-elected subject matter. The elected subject matter have been identified supra.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 and 16 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the instant application, compounds of Formula I are claimed with R^1 , R^2 , R^3 are recited to include noninterfering substitutents; and L^1 and L^2 are recited to be C_1 - C_{10} optionally substituted alkylene or C_2 - C_{10} optionally substituted alkenylene, wherein one or more said C is optionally replaced by a heteroatom selected from N, O, or S, or further substituted with =O, or both.

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The specification fails to teach compounds covering the entire scope of the claimed invention. For example, due to the open definition of a noninterfering substituent in the specification (page 17, paragraph 54), an indefinite number of substituents would fall under that category as it is not known what the substituent would not interfere with to determine what groups are applicable to that position. The working examples in the specification do not cover a representative number of compounds to cover the entire invention as claimed. Therefore, a person of skill in the art would deem that the Applicant did not possess the entire invention as claimed at the time of filing, and claims 1-14 and 16 do not meet the written description portion of 35 U.S.C. 112, first paragraph. Applicant is encouraged to limit the substituent groups to be consistent with those fully supported by the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 and 16 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the instant application, compounds of Formula I are claimed with R^1 , R^2 , R^3 are recited to include noninterfering substitutents; and L^1 and L^2 are recited to be C_1 - C_{10} optionally substituted alkylene or C_2 - C_{10} optionally substituted alkenylene, wherein one or more said C is optionally replaced by a heteroatom selected from N, O, or S, or further substituted with =O, or both.

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From the language used in the claims, it is not know what the boundary is between what Applicant considers to be the invention and what is not considered to be the invention. For example, one of skill in the art would not know whether a possible group for R¹ would be a noninterfering substituent or an interfering substituent as the specification does not teach the conditions for whether a group interferes or not. Therefore, the person of skill in the art would determine that any possible group would qualify as noninterfering and would lead to an indefinite number of compounds. Therefore, claims 1-14 and 16 do not meet the requirements of 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14 and 16 rejected under 35 U.S.C. 102(b) as being anticipated by Kuroita et al. (USPN 6,468,998).

The instant application claims compounds of the formula

$$(R^1)_n \longrightarrow N \longrightarrow L^1 - X^1$$

$$W$$

where: W is L²-A³; L¹ and L² are optionally substituted

 C_1 - C_5 alkylene with no carbons replaced by a heteroatom; A^1 , A^2 , and A^3 are phenyl; X^1 is CR^3 ; and all other substituents are as defined.

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Kuroita et al. teach a compounds of the formula

which reads on the claimed compounds where n is 0, W is L²-A³, L¹ is C(O), X¹ is CR³,

L² is CH₂CH₂, A¹, A², and A³ are 4-fluorophenyl, and R¹, R², and R³ are hydrogen. See

Example 67, column 30, lines 54-61, and the structure on column 44, lines 1-17.

Kuroita et al. also teach the pharmaceutical composition. See column 5, lines 50-53.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-17 rejected under 35 U.S.C. 103(a) as being unpatentable over Kuroita et al. (USPN 6,468,998).

The instant application claims compounds of the formula

$$(R^1)_n \xrightarrow[N]{} L^1 - X \xrightarrow[A^2]{}$$

where: W is L2-A3; L1 and L2 are optionally substituted

 C_1 - C_5 alkylene with no carbons replaced by a heteroatom; A^1 , A^2 , and A^3 are phenyl; X^1 is CR^3 ; and all other substituents are as defined.

Determination of the scope and content of the prior art (MPEP §2141.01)

$$\mathbb{R}^{1}$$
 \mathbb{R}^{9}
 \mathbb{R}^{9}
 \mathbb{R}^{1}
 \mathbb{R}^{9}
 \mathbb{R}^{1}

with

Kuroita et al. teach compounds of the formula

substitutions as defined. See column 2, lines 34 through column 4, lines 65. Kuroita et al. also teach the pharmaceutical composition. See column 5, lines 50-53.

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Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Kuroita et al. do not teach specifically the compounds of the instant invention.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

Kuroita et al. teach generally compounds with the base formula:

$$\mathbb{R}^{1}$$
 \mathbb{R}^{2} in which X is C(O); \mathbb{R}_{1} is \mathbb{R}_{1} , Y is absent, A, B,

and Ar are phenyl groups, D is an optionally substituted linear alkylene chain having 1 to 8 carbon atoms, and all other substituents are as defined.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to follow the synthetic scheme of Kuroita et al. and make the claimed invention with a reasonable expectation of success. The motivation to do so is provided by Kuroita et al. Kuroita et al. teach the use of the synthesized compounds to antagonize 5-HT₂ to treat glaucoma and other ailments. See column 17, lines 51-63.

Thus, the claimed invention as a whole was *prima facie* obviousness over the combined teachings of the prior art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

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obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim1-17 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 6 of U.S. Patent No. 6,468,998.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to the same art recognized subject matter.

The instant application claims compounds of the formula

$$(R^1)_n \longrightarrow N \longrightarrow L^1 - X^1 \xrightarrow{A^1} A^2$$

where: W is L^2 - A^3 ; L^1 and L^2 are optionally substituted

 C_1 - C_5 alkylene with no carbons replaced by a heteroatom; A^1 , A^2 , and A^3 are phenyl; X^1 is CR^3 ; and all other substituents are as defined.

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'998 teaches compounds of the formula

with

substitutions as defined and its pharmaceutical composition.

'998 does not teach each and every substitution recited in the instant application.
'998 does teach generally compounds with the base formula:

$$\mathbb{R}^{1}$$
 \mathbb{R}^{2} in which X is C(O); \mathbb{R}_{1} is \mathbb{R}^{2} , Y is absent, A, B,

and Ar are phenyl groups, D is an optionally substituted linear alkylene chain having 1 to 8 carbon atoms, and all other substituents are as defined.

Therefore, the compounds of '998 are obvious variants of the compounds of the instant application since '998 teaches some of the variations of the instant application's compounds. Hence, '998 suggests the instant invention.

Conclusion

Claims 1-17 are rejected. Claims 1-17 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Kosack whose telephone number is (571)-272-5575. The examiner can normally be reached on M & W 5:30 A.M.-6:00 P.M. and T & Th 5:30 A.M.-2:00 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M^cKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joseph Kosack Patent Examiner Art Unit 1626

Joseph K. MEKane

Supervisory Patent Examiner

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